REMARKS

Claims 23, 26, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 has been amended herein for clarity as suggested by the Examiner. With this amendment and explanation, it is assumed that the rejection under 35 U.S.C. 112, second paragraph, will be withdrawn.

Claims 1-4, 12, 14, 23, 27 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent No. 5,653,748 to Strecker. Claims 8-11, 13, 26 and 33 are rejected under 35 U.S.C. 103(a) as unpatentable over Strecker in view of United States Patent No. 5,480,423 to Ravenscroft et al. Reconsideration of all claims is respectfully requested.

Strecker discloses a device with a prosthesis implantable in the body of a patient. In the device 10 shown in FIG. 1, an elongated catheter 11 serves as a probe. In the vicinity of its distal end 12, catheter 11 carries a prosthesis 15 held in a compressed position under radial pretensioning by means of a crocheted material 14. Column 6, lines 18-27. Prosthesis 15 is surrounded by a crocheted material 14 formed by a continuous thread, with successive meshes wrapped around the prosthesis alternately on one side or the other, in other words alternately on the right or left side. The initial section 17 of the thread material, located in front of the first mesh 16 associated with the distal end 12 of catheter 11, is pulled through a slot 18 in the catheter wall, pinched in said slot, and then extends through the catheter lumen and out through the distal end of the catheter. A strippable loop 22 is pulled through a knot 21 that closes end mesh 21 which is remote from the distal end, said loop being pulled through two rejected [sic. "beanstandete"] cuts 23, 23' in the catheter wall, and is therefore likewise held axially by pinching. Column 6, lines 31-43. Loop 22, pulled through the loop associated therewith or through a knot 21 formed by pulling together these loops to form end mesh 20, is then pulled in the manner shown schematically in FIG. 1 through the two axially spaced slots 23, 23' in the wall of the catheter and held in place by pinching. The remaining thread material then forms drawstring 24 which extends from the loop of end mesh 20 and permits the crocheted material to be stripped. Column 7, lines 15-27.

Ravenscroft et al. discloses prosthesis delivery. The catheter of Ravenscroft et al. includes three radiopaque markers (tantalum bands). A proximal marker 9 indicates the proximal

end of the stent in the compacted state. A central marker 11 indicates the proximal end of the stent in the expanded state. A distal marker 13 indicates the distal end of the stent. Column 4, lines 62-66. The Examiner recites FIGS. 2a-2f in support of his position. In FIGS. 2-2f, use of the delivery system for positioning a stent in the bile duct is illustrated. Referring to FIG. 2, the system may be used to treat an obstruction 40, such as a tumor, in the bile duct 42. Column 6, lines 36-39. Referring to FIG. 2a, the system is slid axially distally until distal radiopaque marker 13 is positioned axially at a location at least about 1 cm distal of the occlusion 40. Column 7, lines 1-3. The marker 11 indicates the position of the proximal end of the stent in the expanded position and is such that the proximal end of the prosthesis will engage healthy tissue over a length of at least 1 cm. The marker 9 indicates the proximal end of the stent when the stent is in the fully compact form. Column 7, lines 8-15. Referring to FIG. 2b, the sheath is retracted in one continuous motion. Column 7, lines 16-17. Referring to FIG. 2c, as the sheath retraction continues, proximally beyond about 60% of the distance between markers 9 and 13, the frictional force between the stent and the wall of the sheath is overcome by the elastic forces of the stent, removing the tension on the stent, and causing the proximal end of the stent to relax distally (arrow 55). Column 7, lines 37-42. Referring to FIG. 2d, after sheath retraction continues but usually to a point less than marker 9, the proximal end of the expanding (arrows 25) and contracting (arrow 55) prosthesis exits the sheath and engages the lumen wall, forcing open the lumen to its normal diameter and firmly anchoring the stent so that it resists axial motion. Column 7, lines 49-54. Referring to FIG. 2e, the prosthesis is released from the catheter body 4 by drawing the catheter body 4 proximally (arrow 27), which causes the end loops to be positioned at more distal positions along the members 16, until the radial force of the prosthesis causes the members to deflect outwardly (arrows 29), releasing the end loops from the members on catheter body 4, so the end loops expand to full diameter. Column 7, lines 60-67. Referring to FIG. 2f, the catheter is then removed from the body, leaving the prosthesis properly positioned. Column 8, lines 6-7.

Amended Claim 1 is patentable by calling for an apparatus of the type set forth therein, including an expandable prosthesis having first and second ends, means for releaseably securing the prosthesis to the distal extremity of the flexible elongate member and a visual marker overlying the prosthesis intermediate the first and second ends and being capable of being seen

by the operator in the field of view secured to one of the distal extremity of the flexible elongate member and the prosthesis for facilitating placement of the prosthesis in the mammalian body, the visual marker being visually distinct from the means for releaseably securing the prosthesis.

Neither Strecker nor Ravenscroft et al. disclose an apparatus of the type called for in Claim 1, and in particular, an apparatus including an expandable prosthesis having first and second ends, means for releaseably securing the prosthesis to the distal extremity of the flexible elongate member and a visual marker overlying the prosthesis intermediate the first and second ends. The end mesh 20 of Strecker is, as described by its term and visible in FIG. 1, located at an "end" of the prosthesis, and thus is certainly not positioned so as to overlie a prosthesis *intermediate* (emphasis added) the first end and second end of the prosthesis. The radiopaque markers of Ravenscroft et al. do not overlie a prosthesis intermediate the first and second ends of the prosthesis.

In addition, as was discussed in the Background of Applicants' disclosure, radiopaque markers have been known to be affixed to the delivery system as shown in Ravenscroft. Unfortunately, fluoroscopically aided delivery systems undesirably expose the patient and the operating physician to x-rays. In addition, such systems require the use of expensive equipment that can require further expense to set up for a procedure. The claimed apparatus, on the other hand, presents significant improvements over the radiopaque device of Ravenscroft, as it permits the placement of a prosthesis without the need of fluoroscopy. As a result, fluoroscopic equipment set up and film preparation can be eliminated and operator and patient exposure to x-rays minimized. The visual marker also facilitates accurate placement of the prosthesis. Where the prosthesis is a stent or other device that contracts in length during deployment, the visual marker can be utilized to anticipate such contraction in length.

Claims 2-4 and 8-14 depend from Claim 1 and are patentable for the reasons as Claim 1, and by reason of the additional features called for therein.

Amended Claim 23 is patentable by calling for an apparatus of the type called for therein, including an expandable prosthesis having a length and first and second ends, means for releaseably securing the prosthesis to the distal extremity of the flexible elongate member extending along substantially the entire length of the prosthesis in a repeating pattern and a

visual marker overlying the prosthesis intermediate the first and second ends and being capable of being seen by the operator in the field of view secured to one of the distal extremity of the flexible elongate member and the prosthesis for facilitating placement of the prosthesis in the mammalian body, the visual marker being visually distinct from the repeating pattern of the means for releaseably securing. As indicated above, neither Strecker nor Ravescroft et al. disclose an expandable prosthesis having a length and first and second ends, and a visual marker overlying the prosthesis intermediate the first and second ends in combination with the remaining features of the claim.

Claims 26-27 depend from Claim 23 and are patentable for the same reasons as Claim 23, and by reason of the additional features called for therein.

Amended Claim 30 is patentable by calling for an apparatus of the type set forth therein, including an expandable prosthesis, means for releaseably securing the prosthesis to the distal extremity of the flexible elongate member and a visual marker capable of being seen by the operator under direct visualization overlying the prosthesis and distinct from the means for releaseably securing for facilitating placement of the prosthesis in the mammalian body. As indicated herein, neither Strecker nor Ravenscroft et al. disclose an expandable prosthesis and a visual marker capable of being seen by the operator under direct visualization overlying the prosthesis and distinct from the means for releaseably securing for facilitating placement of the prosthesis in combination with the remaining features of the claim.

Claim 33 depends from Claim 30 and is patentable for the same reasons as Claim 30, and by reason of the additional features called for therein.

Claim 35 depends from Claim 30 and is patentable for the same reasons as Claim 30 and by reason of the additional features called for therein. In particular, as indicated herein, neither Strecker nor Ravenscroft et al. disclose an apparatus of the type called for in Claim 35, wherein the expandable prosthesis has first and second ends, the visual marker overlying the prosthesis intermediate the first and second ends.

In view of the foregoing, it is respectfully submitted that the claims of record are allowable and that the application should be passed to issue. Should the Examiner believe that the application is not in a condition for allowance and that a telephone interview would help

further prosecution of this case, the Examiner is requested to contact the undersigned attorney at the phone number below.

Respectfully submitted,

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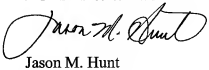

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